

REMARKS/ARGUMENTS

The present claims relate to processes for the preparation of a dry powder formulation for the pulmonary administration of a micronized drug by means of a dry powder inhaler, said process comprising mixing coarse carrier particles having a diameter which lies between 20 and 1000 μm with fine carrier particles having a diameter of less than 10 μm and magnesium stearate in an amount of 0.05 to 2%.

Thus, the technical problem addressed by the present claims is provision of a process for the preparation of a powder formulation for use in a dry powder inhaler. The powder should have good flow properties and deliver the maximum possible proportion of the active particles expelled by the inhaler to the lungs. Good powder flow and dispersion properties are an index of good performance in order to guarantee correct dosage and release by the powder inhaler.

There is nothing in the cited references which would suggest the presently claimed process or the advantages provided thereby. Accordingly, these references cannot make the present claims obvious.

The rejection of Claims 14, 15, 18-25, 28, 29, 31, 32, and 36-39 under 35 U.S.C. § 103(a) in view of the combined disclosures of U.S. Patent No. 6,153,224 (Staniforth) and U.S. Patent No. 6,284,287 (Sarlikiotis et al) is respectfully traversed.

Good flow properties are as a rule expected with sufficiently large particles which have a low surface energy and small contact areas. According to Staniforth, “*small particles with a diameter of less than 10 μm have poor flow and entrainment properties leading to poor dose uniformity*” (see, col. 2, lines 14-17). Staniforth also discloses that “*a Carr’s index of less than 25 is usually taken to indicate good flow characteristics*” (see, col. 15, lines 29-31).

In contrast, as noted above, present Claim 37 relates to a process for the preparation of a dry powder formulation for the pulmonary administration of a micronized drug by means of a dry powder inhaler, *said process comprising mixing coarse carrier particles having a diameter which lies between 20 and 1000 μm with fine carrier particles having a diameter of less than 10 μm and magnesium stearate in an amount of 0.05 to 2%.*

Present Claim 39, which depends from present Claim 37, recites that said powder formulation has a Carr's Index of less than 25.

Therefore, the presently claimed process relates to preparing a powder comprising both coarse carrier particles (with a particle size of 20 to 1000 μm) and fine carrier particles (with a particle size of less than 10 μm) and further comprising magnesium stearate in an amount of 0.05 to 2%, and provides dry powder formulations characterized by good flow properties.

The presently claimed process can be carried out by simply mixing coarse and fine carrier particles having the desired particle size distribution, or, according to the particular embodiment disclosed on page 7, lines 16-22 of the present specification as filed, by treating coarse carrier particles in a mixer *equipped with a rotating element*, as recited in claim 19. As it will be demonstrated below, only this kind of mixer is able to produce "*in situ*" the fine particles of the carrier having a diameter below 10 μm .

As noted above, the other important demand to fulfill for a dry powder formulation is the effectiveness of the release of the active compound particles to the lungs. This also depends on the properties of the carrier, in addition to the specific physicochemical properties of the active compound and the aerodynamic properties of the powder inhaler.

An index of the effectiveness of the release of the inhalable particles of the active compound is the amount of fine particles, the fine particle dose, also designated by FPD or

the fine particle fraction, designated by FPF, determined relative to the total amount of release active compound *in vitro* in so-called cascade impactors or liquid impingers, such as are described in various pharmacopoeias. The dry powder formulation prepared with the process of the invention, besides being free flowing, improves the delivering of the medicament to the lungs, as demonstrated in the examples provided in the present specification.

Specifically, in Example 1, the performance of a powder formulation comprising coarse carrier particles having a diameter comprised between 90 and 150 μm and fine carrier particles of less than 10 μm is shown. The particle size distribution is reported in Figure 1. The formulation is provided with a very good flowability (Carr's Index of 17, well below the 25 value usually taken to indicate good flow characteristics) and can deliver a higher fraction of fine particles of active ingredient with respect to a standard preparation not containing the finer particles (*see*, Table 2 on page 12 of the Application). These results show that the flow properties of the carrier are not affected by the presence of fine particles having a diameter of less than 10 μm .

Similar results are presented in Example 2 in which the preparation containing the fine particles has a Carr's Index of 11 and is able to improve the FPD (μg) from 60.1 to 80.9, with a FPF (%) from 32.2 to 47.9.

In Example 3 the preparation of a BDP/lactose/magnesium stearate ternary mixture is reported. The lactose carrier is the same as in Example 1 and therefore made of a coarse fraction of particles having a diameter comprised between 90 and 150 μm and a fine fraction of particles having a diameter of less than 10 μm . Lactose particles were mixed with 0.25% by weight of magnesium stearate, and the micronized active ingredient was added to the mixture.

The flowability characteristics as well as the aerosol performances are reported in Table 4 and further demonstrate that powders prepared with the process of the invention maintain good characteristics of flowability providing at the same time significant increase of the fine particle fraction, with respect to a comparative preparation not containing the fine particle fraction.

As pointed out before, it is well known to those skilled in the art that the flowability of a powder is such an important property that nearly all handling processes are affected to a greater or lesser extent. In the case of dry powder aerosol formulations, flowability of both drug and carrier particles plays an important role in mixing, capsule-filling, metering of the dose and aerosolization. Flowability of a powder is, *inter alia*, a function of particle size, *size distribution* and interparticulate forces.

Staniforth discloses a dry powder that includes an active compound, a carrier with an aerodynamic diameter of 20-1000 microns, and an additive. The preferred range of particle sizes lies in the range of 60 μm to 180 μm .

Staniforth also discloses a “gentle” milling process to treat the surface of the carrier particles wherein smaller grains of the carrier material are produced. The treatment step is always present in Staniforth’s process and may be carried out before or after the addition (by mixing in a tumbling blender, for example Turbula Mixer – col. 8, lines 45 to 50) of the additive material to the carrier or, alternatively, after the addition of the additive material and of the active particles (*see*, col. 8, lines 51-55; and col. 8, line 66, to col. 9, line 5). The treatment step is a milling step (*see*, col. 9, line 39), preferably performed in a ball mill (*see*, col. 9, line 43). Alternatively, a different milling technique may be used, for example using a recirculated low fluid energy mill or other methods, for example sieving, or cyclone treatment (*see*, col. 9, lines 63-67).

The size of the particles removed as small grains during the treatment is not disclosed in Staniforth. However WO 95/11666 (a copy of which was submitted with the Information Disclosure Statement filed on July 29, 2003) of the same inventor discloses that this same process provides small grains with 1-5 microns (*see*, page 11, lines 2-4).

Therefore, Staniforth discloses a different method, which provides a different composition.

In fact, the carrier particles of Example 3 of Staniforth, consisting of coarse lactose particles having small grains reattached to their surface (sample X), have a very poor flowability, as reflected by a Carr's Index of 36.4, and even the addition of 1% by weight leucine (samples Y and Z) only slightly improves the flow characteristics, and the Carr's Index (of 32.1 and 35.6, respectively) remains well above the 25 value, index of good flow properties.

In sharp contrast, the Carr's index values reported in Tables 2, 3, and 4 of the present application demonstrate that the presently claimed powder formulations do, in fact, exhibit good flowability properties, at the same time improving FPD and FPF.

Therefore, in contrast to Staniforth, the fine fraction of particles with a diameter below 10 μm of the instant application allows the modulation of the interparticle forces between carrier particles and micronized drug (*see*, page 6, lines 21-25, of the present specification), thereby producing a better dispersion of the active particles in the respiratory tract to improve the respirable fraction of the active compound, without affecting the flowability of the powder (*see*, page 7, lines 13-18 and 31-34, of the present specification).

On the other hand, Staniforth, teaches away from the use of a fine carrier fraction having a diameter below 10 μm : "*small particles with a diameter of less than 10 μm may be*

deposited on the wall of the delivery device and have poor flow and entrainment properties leading to poor dose uniformity" (see, column 2, lines 13-16).

Moreover, in Staniforth magnesium stearate is not the additive of choice, but a material that may be used but is not preferred (see, col. 2, lines 61-62), that according to Example 13, when added in an amount of 1.5% to a powder composition may provide satisfactory results in terms of a respirable fraction, *but does not meet the other important requirement of retaining homogeneity* (see, col. 24, lines 2-7). Staniforth indeed states that *"it is particularly advantageous for the additive material to comprise an amino acid"* and that *"leucine is the preferred amino acid"* and the preferred additive (see, col. 5, lines 12-18 and lines 25-26). Therefore, Staniforth teaches away from the use of magnesium stearate in the composition.

As pointed out before, Staniforth discloses on col. 15, line 29 that a Carr's index of less than 25 provides good flow characteristics. As a matter of fact, the carrier of Staniforth shows a Carr's index of 36.4 which is only slightly improved to 35.6 or 32.1 by addition of 1% leucine and 1% leucine in combination with the milling treatment, respectively. In other words, even the preferred carrier of the reference document has a very poor flowability.

Sarlikiotis et al discloses mixing the active compound with the carrier (or excipient) so that the active compound particles adhere to the carrier (excipient) particles and thereby almost *round excipient particles coated with active compound result* (see, col. 2, lines 56-64). The particles so obtained are defined as *core agglomerates* of the constituents (see, col. 4, lines 60-65).

Sarlikiotis et al does not teach or suggest preparing a dry powder for pulmonary inhalation by mixing fine carrier particles having a diameter below 10 μm with coarse carrier particles in order to decrease the interparticle forces between the active substance and the carrier particles and even less to add an additive in order to further improve the respirable

fraction of the delivered drug. To the contrary, Sarlikiotis teaches away from the use of additives or auxiliary substances:

at present most of the pharmaceutically customary auxiliaries cannot be used in pharmaceutical forms for inhalation, as the toxicological behaviour of these substances on pulmonary administration is still largely unknown (see, col. 1, lines 42-48).

Therefore, there were no reasons or hints for the skilled in the art, at the time of the present invention was made, to combine the teachings of Staniforth (whose preferred additive is an amino acid, the most preferred one being leucine and declares that particles with a diameter of less than 10 μm can lead to poor dose uniformity) with those of Sarlikiotis et al (that discourages the use of additives and only discloses mixing an active ingredient with a carrier (or excipient) to coat the carrier crystals with the active compound forming agglomerates).

In any case, the combined teaching of Staniforth and Sarlikiotis et al cannot lead to the presently claimed process.

Sarlikiotis et al teaches to prepare *core agglomerates* made of round or almost round particles only consisting of excipient particles having a particle size of 200 to 1000 μm , preferably between 300 μm and 600 μm , and active compound particles having a particle size of 0.01 μm to 10 μm . No additional excipient particles or binders (*see*, col. 1, line 10) or additive (customary auxiliaries) are used (*see*, col. 1, lines 42-46) due to concerns about their potential toxic effects. Thus, Sarlikiotis et al suggests neither to utilize excipient particles having a particle size below 200 μm (even less below 10 μm) nor to the use of any additives.

Indeed, Sarlikiotis et al teaches away from the use of excipient particles having a mean particle size below 200 μm , by asserting that preparations of the prior art containing

excipient particles having a particle size of 80 μm to 150 μm or compositions comprising a first auxiliary having a mean particle size of about 20 μm and a second auxiliary component having *smaller particles of approximately 10 μm particle size*, present the disadvantage of poor flow properties (*see*, col. 2, lines 17-20)).

Moreover, an essential feature of the excipient utilized by Sarlikiotis et al in order to prepare its core agglomerates, is a roughness of more than 1.75, to allow the active compound particles to adhere to the excipient particles (*see*, col. 2, lines 56-64). To be endowed with this particular degree of rugosity, the excipient of Sarlikiotis et al can not be exposed to a process which either originates “small grains” (as it is the case of milling of Staniforth), or can produce *in situ* a fine fraction of particles below 10 μm (as in the case of mixing in a mixer equipped with a rotary element as described in the present specification).

Instead, Sarlikiotis et al, who wants to prepare core agglomerates of excipient and active ingredient, uses a Turbula mixer (*see*, Examples 2 and 4 to 7) or a Diosna mixer. Applicants submit herewith, as Exhibit A, a description of a Turbula mixer, and a description of other mixing equipment, taken from Pharmaceutical Dosage Forms, vol. 2, pages 29-43, is being submitted with the Information Disclosure Statement being filed herewith. As can be appreciated, a Turbula mixer can reach as maximum speed of only 90 rpm.

In contrast, the class of mixers utilized in the present application is characterized, indeed, by a higher speed and/or by the presence of a rotating element.

Diosna is a high-shear mixer usually utilized to granulate and hence to form agglomerates.

In the case of the present claims, the operating conditions are defined by the use of a mixer selected from those with a stationary or rotating body equipped with a rotatory element

(*see*, Claim 19) which operates at higher speed (from 100 to 300 rpm) to produce "*in situ*" a fine fraction of the carrier particles (*see*, Claim 20).

For all of these reasons, the rejections should be withdrawn.

The rejection of Claims 14, 15, 18-25, 28, 29, 31, 32, and 35-39 under the judicially-created doctrine of obviousness-type double patenting in view of Claims 1-21 of U.S. Patent No. 6,641,844 (Musa et al) is being obviated by the filing herewith of a duly executed Terminal Disclaimer over Musa et al. Accordingly, the rejection is no longer tenable and should be withdrawn.

Applicants submit that the present application is now in condition for allowance, and early notification of such action is earnestly solicited.


Respectfully submitted,

OBLON, SPIVAK, McCLELLAND,
MAIER & NEUSTADT, P.C.

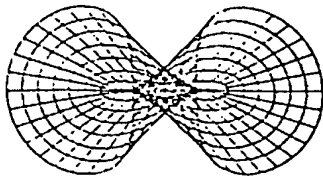
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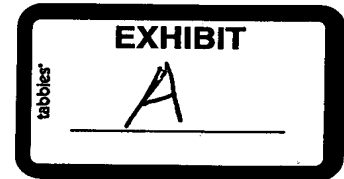
TURBULA

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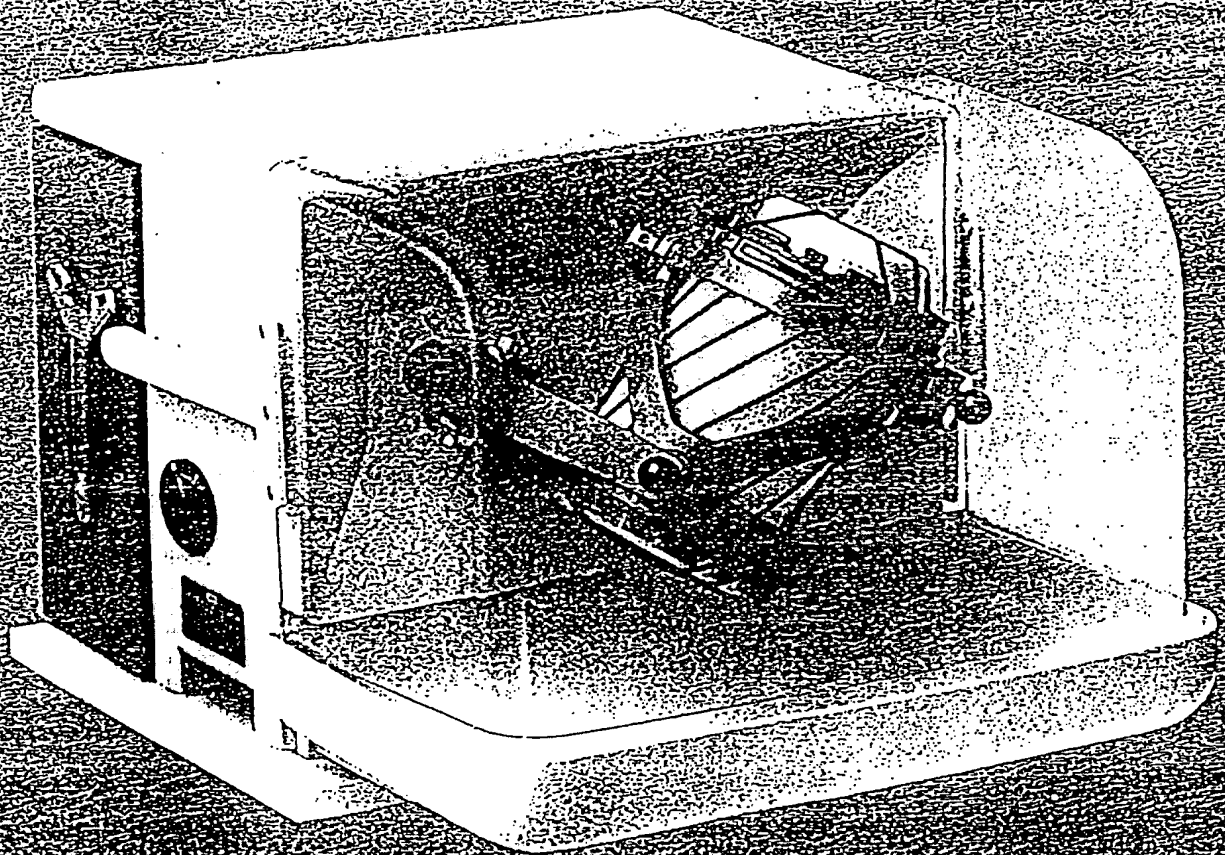
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Betriebsanleitung
Mode d'emploi
Operating Instruction



MELONI CENTR-O-FILTER S.n.c.

Via S. VERRO 31 - 20141 M I L A N O
TEL. : (02) 84.63.613 * 84.63.996
TELEFAX: (02) 84.33.044



TURBULA[®] Maschine T2C



SEV-geprüft
Schweiz. Elektrotechnischer Verein

Hersteller:
Willy A. Bachofen AG, Maschinenfabrik,
Utengasse 15/17, CH-4005 Basel

Maschinen-Nr.:

910362

(Bitte in allen Korrespondenzen angeben)

Technische Daten

Stromart:	Wechselstrom	<input checked="" type="checkbox"/>
	Drehstrom	<input type="checkbox"/>
Spannung:	Volt	220
	Hz	50
Frequenz:	Hz	50
	Ampère	0.9
Stromaufnahme:	Ampère	0.9
	Watt	180
Leistung:	Watt	180

Motor:	Typ 63, nach IEC-Norm
Motordrehzahl:	1400 UpM
Behältergrösse:	Maximal 130 mm Ø und 215 mm Länge
Abmessungen:	470 mm breit, 560 mm tief, 670 mm hoch (offene Schutzhaube)
Gewicht:	ca. 34 kg
Ausgangsdrehzahl:	20/30/42/62/90 UpM
Zubehör:	1 Schlüssel für Einspannvorrichtung 1 Fixierstab zum Spannen der Kette 1 Betriebsanleitung

Maschinenbeschreibung

Die TURBULA-Maschine besteht aus:
- dem Gehäuse (401), der Grundplatte (402) mit den Antriebsorganen und der Schutzhaube (407)
- dem Arbeitskorb (201) und der wegnehmbaren Auffangschale (405)
Das Gehäuse sowie die daran befestigte Auffangschale sind aus Leichtmetall-

guss. Fünf Drehzahlstufen sind wählbar durch Umlagen eines elastischen Rundriemens. Der Antriebsmotor ist durch einen Schutzschalter mit thermischer Schnellauslösung gesichert. Eingeschaltet wird die Maschine durch Betätigung des Drehschalters auf der linken Maschinenseite. Dies kann nur bei gesenkter Schutzhaube geschehen. Das Ausschalten der Maschine erfolgt durch Betätigung des Drehschalters. Die Schutzhaube kann erst gehoben werden, wenn die Zeituhr abgelaufen ist. Nur bei geöffneter Schutzhaube ist der Zugang zum Maschinenkorb möglich. Der Maschinenkorb dient zur Aufnahme des Arbeitsbehälters und wird zum Be- und Entladen in der Beschickungsstellung automatisch fixiert (roter Kugelgriff oben). Beim Senken der Schutzhaube wird die Verriegelung selbsttätig gelöst.

Arbeitsweise

Durch ein bewährtes Bewegungsprinzip (Umstülpungskinematik) wird das Beschickungsgut im Arbeitsbehälter durch Antrieb über zwei Gelenkbügel (202) einem dreidimensionalen Bewegungsvorgang unterworfen. Das Zusammenwirken der dreidimensionalen Bewegungsart führt dazu, dass das Mischgut andauernd in zwei sich wechselweise vertauschende, pulsierende Wirbel versetzt wird. Die Intensität des Mischprozesses kann durch Änderung der Drehzahl und des Füllungsgrades im Behälter beeinflusst werden.

Aufstellen / Transport

Die Maschine wird mit 2 Schrauben (M8) auf einem stabilen Tisch festgeschraubt. Als Auflage dienen, in der Grundplatte eingelassene Gummiprofile. Zum Tragen der Maschine sind seitlich am Gehäuse Ausschnitte.

Elektrische Anschlüsse

Die Maschine ist fertig verdrahtet. In der leicht zugänglichen Anschlussdose (502) befinden sich die Strom- und Erdleiterklemmen. Bei Maschinen mit 3-Phasen-Motor muss der Anschluss von einem Elektriker vorgenommen werden (siehe Zeichnung Nr. 43568). Dabei ist auf die Drehrichtung des Motors zu achten (entgegen des Uhrzeigersinns). Maschinen mit 1-Phasen-Motor werden ab Werk mit Kabel und Stecker geliefert.

Motorschutzschalter (505)

Um eine Überlastung des Motors z. B. bei Spannungsschwankungen im Netz oder bei einem mechanischen Defekt auszuschliessen, ist ein Schutzschalter mit thermischer Überstrom-Schnellauslösung eingebaut.

Arbeitsbehälter

Die Wahl des Arbeitsbehälters ist freigestellt, das heisst es können Behälter aus Kunststoff, Glas, Aluminium, Stahl usw. verwendet werden, soweit sie nicht die durch den Maschinenkorb vorgeschriebene Grösse von 130 mm Ø und 215 mm Länge überschreiten und stabil genug sind, um sich nicht unter der Last des Beschickungsgutes zu deformieren und mit einem dichtschiessenden Verschluss versehen sind. Es können Behälter eingespannt werden bis zu einem Maximalgewicht von 10 kg brutto.

Inbetriebnahme

Durch Senken der Schutzhaube (407) wird die Verriegelung des Maschinenkorbes (201) gelöst und gleichzeitig die Blockierung des Motorschalters aufgehoben. Die Maschine kann also nur bei gesenkter Schutzhaube durch Betätigung des Drehschalters (505) in Betrieb gesetzt werden.

Einspannen und Ausspannen der Arbeitsbehälter

Bei geöffneter Schutzhaube (407) ist der Maschinenkorb (201) langsam von Hand zu drehen bis der rote Kunststoffknopf (225) nach oben zeigt und die Verriegelung einrastet. Der Maschinenkorb (201) schliesst nach oben und unten mit einer Spannkronen (207) ab; zwischen beiden sind endlose Gummispanner eingespannt. Der eingesetzte Arbeitsbehälter wird dadurch befestigt, dass mit dem Spannschlüssel (601) die rechte bewegliche Spannkronen (207) gegenüber der linken feststehenden Kronen im entgegengesetzten Uhrzeigersinn so lange verdreht wird, bis die Gummispanner den Behälter fest umschliessen. Axial wird der Arbeitsbehälter durch jeweils zwei gekreuzte Gummispanner gesichert. Zum Ausspannen der Arbeitsbehälter wird in umgekehrter Reihenfolge gearbeitet. Nachdem der Maschinenkorb in der Verriegelung eingerastet ist, werden auf der rechten Seite die gekreuzten Gummispanner gelöst, die Spannkronen mit dem Spannschlüssel erst etwas angezogen und dann bei gleichzeitigem Niederdrücken der Sperrklinke (206) langsam dem Zug nachgebend gelockert, bis diese entspannt sind und der Behälter dem Maschinenkorb entnommen werden kann.

Antriebsdrehzahlen

Durch Umlagen des elastischen Rundriemens (151) auf den im Gehäuse befindlichen Stufenscheiben können fünf Drehzahlen gewählt werden: 20/30/42/62/90 UpM. Die Drehzahl ist den jeweiligen Arbeitsbedingungen anzupassen. Zu den Stufenscheiben gelangt man durch die Tür (410) an der rechten hinteren Gehäusesseite.

Spannen, resp. Wechseln der Kette

Die Rückwand wird bei gehobener Schutzhaube und nach dem Herausnehmen der Schraube in der Mitte oben entfernt und man hat so freien Zugang zum Antriebsteil. Die Rund- (151) und Flachriemen (150) haben eine Eigenvorspannung und brauchen keine Nachspannung. Die Rollenkette (148) wird wie folgt gespannt.

1. Schraube (132) lösen
2. Bohrung Ø 4 mm der Flachriemenscheibe (108) und Bohrung der Exzenterbüchsen (107) mit Fixierstift (602) verbinden.
3. Flachriemenscheibe (108) drehen, bis Kette (148) gespannt, resp. entspannt ist.
4. Schraube (132) festziehen
5. Fixierstift (602) herausziehen

Wartung

Die Maschine ist praktisch wartungsfrei. Nur die Rollenkette sollte zweimal jährlich eingefettet werden. Die Spannung der Kette soll periodisch überprüft und bei Bedarf nachgezogen werden.

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TURBULA® Unit Type T2C



Manufactured by:
Willy A. Bachofen AG, Maschinenfabrik,
Utengasse 15/17,
CH-4005 Basle/Switzerland

No. of machine: _____

(Please always refer to in correspondence)

Technical Data

Power supply:	A.C.	<input type="checkbox"/>
	3-phase	<input type="checkbox"/>
Voltage:	volts	<input type="checkbox"/>
Frequency:	Hz	<input type="checkbox"/>
Charging rate:	amperes	<input type="checkbox"/>
Motor rating:	watts	<input type="checkbox"/>
Motor:	type 63, to IEC specification	
Speed:	1400 r.p.m.	
Maximum container size:	130 mm in diameter and 215 mm long	
Dimensions:	470 mm wide, 560 mm deep, 670 mm high (with open protective cover)	
Weight:	approximately 34 kg	
Initial speeds:	20/30/42/62/90 r.p.m.	
Accessories:	1 key for the clamping device 1 fixing bar for chain tightening 1 set of instruction for use	

Description of the Machine

The TURBULA unit includes the following elements:

- casing (401), mounting plate (402), together with driving mechanisms and protective cover (407)
 - cage (201) provided with the removable collecting vessel (405).
- Both the casing and the collecting vessel fastened to it are cast from light alloy. Each of the realizable five speeds can be chosen by adequate positioning of a round elastic belt on the transmission step pulley. Safe operation of the driving motor is ensured by a quick-action thermal cutout switch. The machine is started by actuating the rotary switch fitted to the left-hand side of the unit provided, however, that protective cover has been lowered. The machine is stopped by actuating the rotary switch. The protection cover can only be lifted after the indicated lapse of time. Access to the cage is possible only when the protective cover is open. The cage itself provided to accommodate the service container is fixed automatically (with the red ball-shaped knob at the top) in the charging position for filling and emptying. Lowering the protective cover results in an automatic release of the locking mechanism.

Mode of Operation

By making use of a service-proved kinetic principle (reversal kinematics), the fed charge in the service container is subjected to the action of a three-dimensional motion produced by a drive via the two knuckle joints (202). Due to the compound action of the three-dimensional motion, a continuous motion implying two alternating intermittent vortices is imparted to the mixed stock. The intensity of the mixing process can be controlled by varying speed and/or the degree of container loading.

Installation / Transport

The unit is fastened to a solid table with two screws (M 8) and supported by countersunk rubber moldings in the mounting plate. To enable the machine to be carried by hand, lateral recesses are provided in the casing.

Electric Power Supply

The units are supplied ready wired-up. Both power and earth lead terminals are provided in the easily accessible terminal box (502). The connection of units with three-phase motor to the mains must be performed by an electrician (see drawing no. 43568). Care should be taken to ensure the (counterclockwise) sense of motor rotation. Single-phase motor units supplied ex works are provided with cable and plug.

Motor Circuit Breaker (505)

To prevent motor overloading, possible due to factors such as variations in mains voltage or mechanical defects, an overload cutout switch with quick-action overcurrent release has been incorporated.

Service Containers

The choice of a suitable service container is free, i.e. containers made of plastics, glass, aluminium, steel, and other materials may be used unless the size limits imposed by the dimensions of the cage - 130 mm in diameter and 215 mm long - are exceeded, and provided that their mechanical strength is sufficiently high to prevent deformation under the fed charge, and that they are equipped with a tightly sealed closure. Containers up to a maximum gross weight of 10 kg may be introduced.

Starting UP

By lowering the protective cover (407), the locking mechanism of the cage (201) and, at the same time, the motor-circuit switch blocking are released. Owing to this, the unit can be put into operation by actuating the rotary switch (505) only when the protective cover has been lowered.

Fitting in Position and Removing the Service Containers

When the protective cover (407) has been opened, cage (201) is slowly turned by hand until it engages in the locking device, with the red plastic button pointing upwards. Both top and bottom plates of the cage (201) are gripping heads (207); between the two heads, end-less rubber straps are fitted. After fitting, the service container is fastened by turning the right-hand movable clamping head (207) counterclockwise to the left-hand stationary clamping head (207) with the tightening key (601) until the rubber straps around the container are tightly stretched. Axially, the service container is held in position with two crossed rubber straps (211) provided at each end.

To remove the service containers, the above-described sequence of operation is reversed. When the cage has been disengaged from the locking device, the crossed rubber straps on the right side are loosened; the gripping head is, at first, slightly screwed up with the tightening key and thereafter released, with depression of the holding pawl (206) and simultaneous slow yielding to the pull until the rubber straps are free of tension. Then the container can be removed from the cage.

Driving Speeds

By adequate positioning of the round elastic belt (151) on the step pulleys accommodated in the motor casing, one of the five realizable speeds - 20/30/42/62/90 r.p.m. - may be chosen. The speed should be chosen in dependence on the actual operating conditions. The step pulleys are accessible through the door (410) in the right-hand rear wall of the casing.

Tightening up or changing of the chain

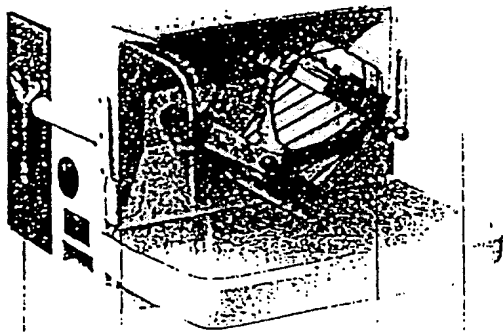
To remove the back wall, open the protection cover and take out the screw in the middle of the upper part of the wall, thus making the driving member easily accessible. Neither the round belts (151) nor the flat ones (150) require retightening due to the initial strain previously imparted to them. Tightening up of the roller chain (148) is performed in the following way:

1. loosen screw (132)
2. connect the \varnothing 4 mm bore in the flat-belt pulley (108) with the bore in the eccentric bushes (107) by dowel pin (502)
3. turn the flat-belt pulley (108) until the chain (148) is stretched or released.
4. tighten the screw (132)
5. remove the dowel pin (602)

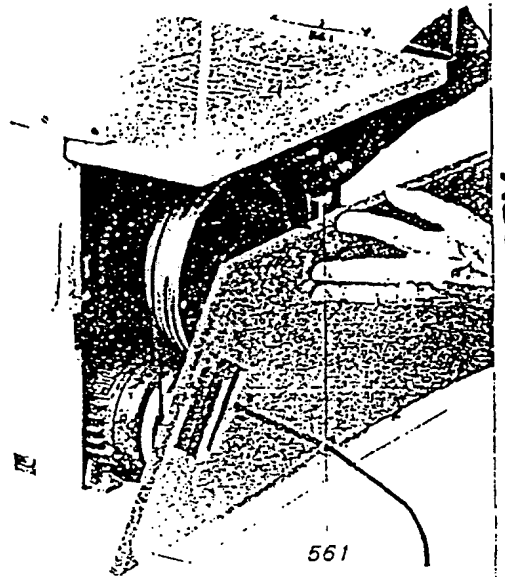
Maintenance

The unit is virtually maintenance-free, it is only the roller chain which needs grease-lubrication in six-month intervals. Periodic checking of the chain tension and its retightening are necessary, if required.

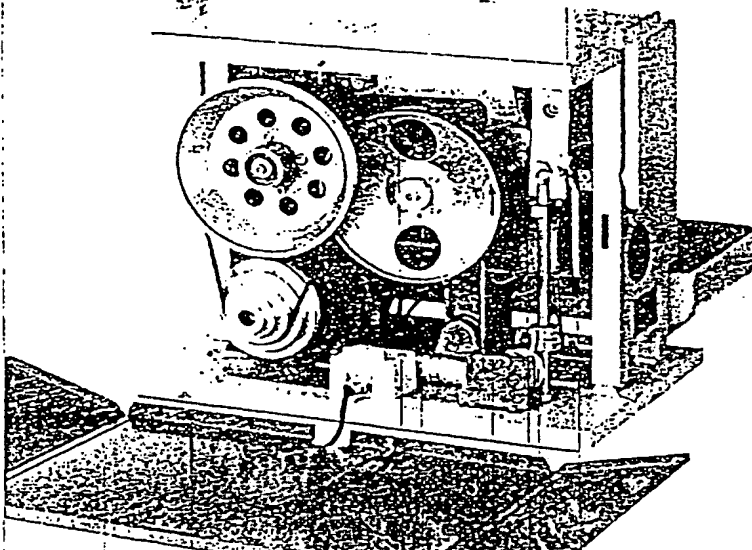
BEST AVAILABLE COPY



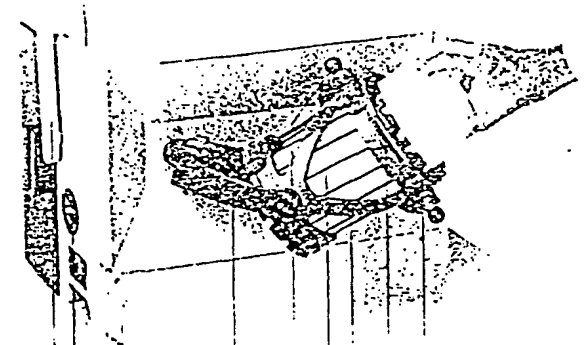
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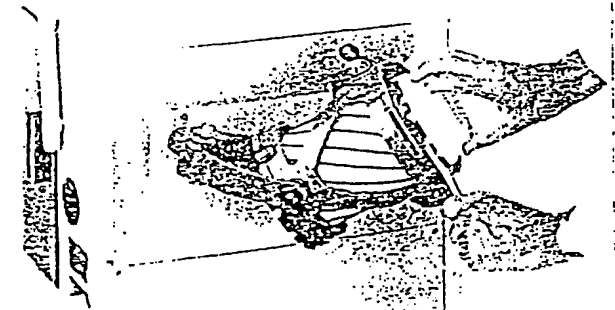
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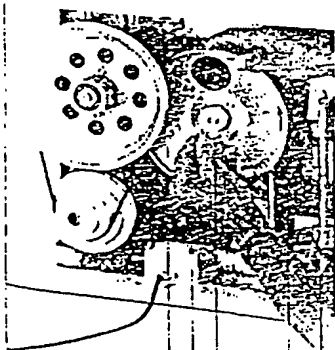
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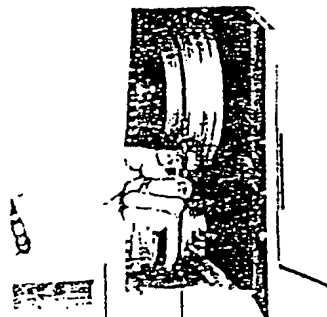
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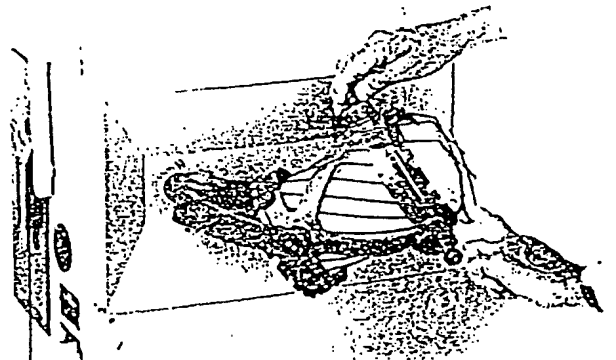
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502 565



402
401 151



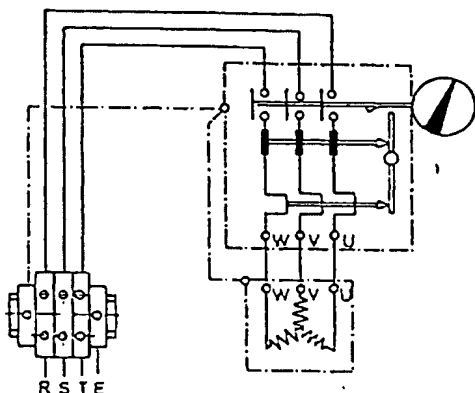
562

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Drehstrom: 3 Phasen

courant triphasé

three-phase current

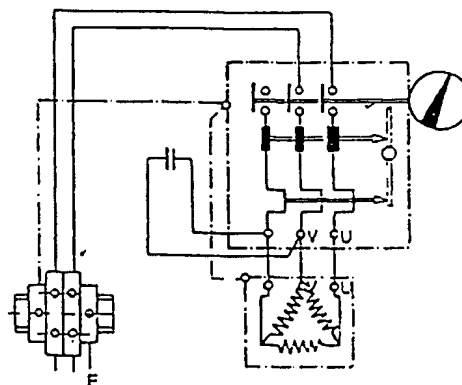


Erdleiter: gelb/grün
terre: jaune/vert
ground wire: yellow/green

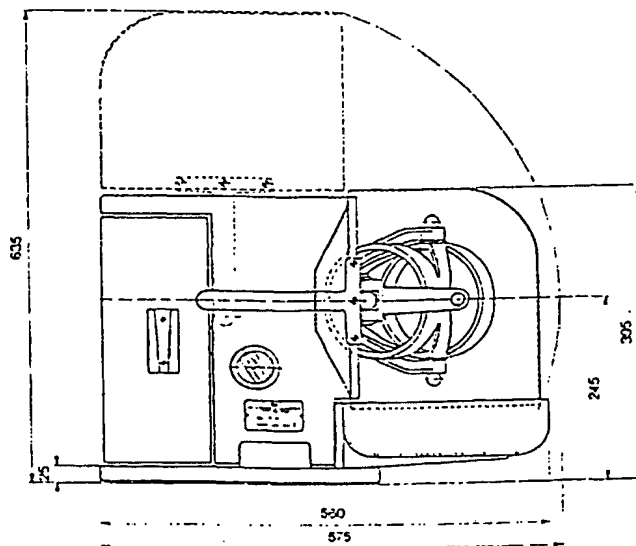
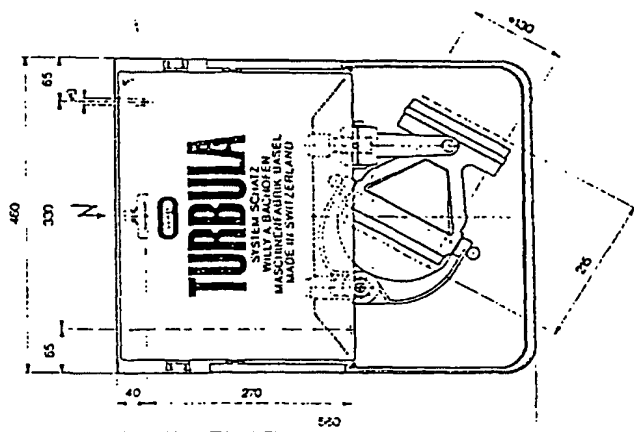
Wechselstrom 1 Phase
mit kapazitiver Hilfsphase

courant alternatif monophasé
avec condensateur auxiliaire

alternating current
1 phase
with capacitive booster phase



Erdleiter: gelb/grün
terre: jaune/vert
ground wire: yellow/green



Willy A. Bachofen AG Maschinenfabrik, Basel